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Attachment 3

JUN 15 2005

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the Palomar LuxIR handpiece is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant: Palomar Medical Technologies, Inc.

Address: 82 Cambridge St.
Burlington, MA 01803

Contact Person: Marcy Moore

Telephone: 919-363-2432

Preparation Date: February 10, 2005

Device Trade Name: Palomar LuxIR Handpiece

Common Name: Infrared Handpiece

Classification Name: Infrared Heating Lamp
(21 CFR 890.5500).

Legally-Marketed Predicate Device: K033768
Cutera Optional Infrared Handpiece

System Description:

The Palomar LuxIR Handpiece delivers infrared light with a wavelength of 800-1800 nm. The complete system consists of a power source, chiller, a footswitch, and a handpiece connected to the power unit with an umbilical. In standard use, the handpiece is held in firm contact with the skin. The handpiece tip is water-cooled to provide active skin cooling. System parameters and other system features are controlled from the user interface panel on top of the power unit.

Intended Use of the Device:

The Palomar LuxIR Handpiece is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the Palomar LuxIR Handpiece may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

Performance Data:

The differences in the specifications of the Palomar LuxIR Handpiece and the predicate device do not result in different performance or raise new questions of safety or efficacy.

Conclusion:

Based on the foregoing, the Palomar LuxIR Handpiece is substantially equivalent to the legally-marketed claimed predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2005

Palomar Medical Technologies Incorporated
C/o Ms. Marcy Moore
Manager of Clinical Studies
131 Kelekent Lane
Cary, North Carolina 27511

Re: K050370

Trade/Device Name: Palomar LuxIR Handpiece
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: May 6, 2005
Received: May 9, 2005

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050370

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Device Name: Palomar LuxIR Handpiece

Indications for Use:

The Palomar LuxIR Handpiece is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the Palomar LuxIR Handpiece may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

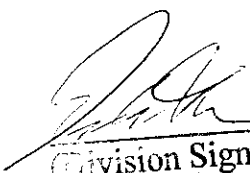
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050370